REMARKS

Claims 33-52 were pending in the application and were rejected. Claims 33, 34, 40, 42, and 44-47 are amended and claim 53 is new. None of the amended or new claims introduce new subject matter. Amended claims 33 and 40 are supported at page 6, line 26 through page 7, line 13 and Examples 1-3 on pages 9 through 17, all of which pertain to methods of treatment not related to treatment of coronary ischemia or angina. Claims 42, and 44-46 are amended to correct antecedent basis. New claim 53 is supported by original claim 2.

In response to the Examiner's objection of the Abstract, Applicant submits an amendment making the requested correction.

Applicant further corrects typographical errors in the specification. The amendment within Table 3 is supported by the title of Table 3.

In response to the Examiner's objections to claims 33 and 40, amendments to the claims make the appropriate corrections or render them moot.

35 USC § 112, First Paragraph

Claims 33-52 were rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that the subject matter of the claims is not described in the specification in a manner to reasonably convey that the inventor had possession of the entire genus of peptides derivable from human lactoferrin or modified peptides or metabolites or functionally equivalent analogues, at the time the application was filed.

The present claims render the rejection moot. The claims define the peptides used in the treatment as a genus of peptides all containing an amino acid sequence of at least 7 amino acids in length selected from the the amino acid sequence that is amino acids 12-40 of human lactoferrin counted from the N-terminal end or a similar peptide modified such that C-20 is replaced by A, Q-22 is replaced by K and N-26 is replaced by D. Thus they are structurally identified, as supported in the specification.

Furthermore, the peptides are defined functionally as well, as "active in stimulating VEGF-mediated angiogenesis," as supported in the specification. Thus the genus of peptides

used in the claimed methods is described by structure and function and Applicant asserts that the full scope of the genus in the claims is adequately described in the disclosure.

Still further, the present claims are directed to a method of treatment of a vascular disease or states of tissue hypoperfusion leading to hypoxia or ischemia in a patient, with the proviso that the method does not pertain to coronary ischemia. Thus, the treatable condition is recited with specificity and is supported by the specification.

Claims 33-52 were further rejected under 35 USC § 112, first paragraph, as failing to provide enabling description to use the method as claimed.

Since the present claims are directed to a method of treatment for those vascular diseases or states of tissue hypoperfusion that lead to hypoxia or ischemia in a patient, with the proviso that the method does not pertain to coronary ischemia, the claims are directed to a particular disease state rather than to a broad array of vascular diseases. The specification teaches that those clinical conditions would benefit from enhanced $VEGF_{165}$-induced angiogenesis.

The Examiner further stated that none of the claimed genus of peptides were shown to be useful in the treatment. As amended, claims 33-39 are directed to treatment with human apo-lactoferrin, so these claims are outside of the rejection, per the Examiner's remarks on enabled subject matter (Off. Act., p. 6 bottom). Claims 40-52 use human apo-lactoferrin, human lactoferricin and the recited peptides in the method of treatment.

The breadth of the amended claims is restricted to a limited genus of peptides described structurally and functionally, as explained above. The claims are also restricted to a limited genus of vascular disease or states of tissue hypoperfusion leading to hypoxia or ischemia in a patient, with the proviso that the method does not pertain to coronary ischemia. Claims 34 and 47 restrict the treatable disease states to treating impending stroke, manifested stroke, and peripheral artery occlusive disease. Claims 35 and 48 restrict the treatable disease states to vascular disease, state of tissue hypoperfusion, or state of depressed VEGF induced angiogenesis associated with peptic ulcer, leg ulcer or local or generalised hair loss.

The claims are restricted to treatment of disease rather than prevention.

Furthermore, the specification contains working examples of treatment with human apo-lactoferrin to demonstrate additional stimulatory effect on VEGF-stimulated angiogenesis.

For these reasons, Applicant asserts that the claims are supported by enabling description and respectfully requests that the rejection be reconsidered and withdrawn.

35 USC § 112, Second Paragraph

Claims 33, 34, 40, 42, 46, 47, and 49-52 were rejected under 35 USC § 112, second paragraph, as being indefinite.

Claims 33 and 40 have been amended to state with definiteness, "tissue hypoperfusion leading to hypoxia or ischemia". Claims 34 and 47 have been amended to delete the two phrases the Examiner stated were unclear. Claims 40 and 42 have been amended to correct all the antecedent basis issues. Claim 42 has been amended to state with definiteness "amino acids 16-40 or amino acids 18-40". Claim 46 has been amended to state the sequence with definiteness. For all the above reasons, it is believed all the claims are now definite.

35 USC § 102

Claims 33-38 and 40-51 were rejected under 35 USC § 102 as being anticipated by Mamoru et al. (JP 07-278011). JP 07-278011 is directed to a method of treating angina pectoris. The claims, as amended, are not directed to treatment of angina pectoris or ischemic heart disease. JP 07-278011 does not disclose a method for treatment or prevention of vascular disease or tissue hypo-perfusion, not pertaining to angina pectoris or coronary ischemia. Therefore, JP 07-278011 does not anticipate claims 33-38 and 40-51.

Even further, claims 34 and 47 are directed to treating stroke and peripheral artery occlusive disease, which are not disclosed by JP 07-278011.

For all the above reasons, the claims are novel over JP 07-278011.

Claims 33-52 were rejected under 35 USC § 102 as being anticipated by Wu et al (US 5,712,247 ('247). The basis for the rejection is traversed.

Claims 33-52, as amended, are directed to a method for treatment of vascular disease or tissue hypo-perfusion, not pertaining to coronary ischemia.

The Examiner's rejection is based entirely on the premise that patients needing cardiopulmonary bypass or cardio-catheterization (treatments disclosed in Wu et al) usually have angina and the resulting myocardial ischaemia. Since Wu et al doesn't actually disclose treatment for angina and myocardial ischaemia, the Examiner's grounds for the rejection stem from an argument of inherent anticipation. It is accepted law that anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation. (See: *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991)). The Examiner has already conceded that patients needing cardiopulmonary bypass or cardio-catheterization do not *necessarily* suffer from angina and myocardial ischaemia. (The Examiner stated that the patients *usually* have angina). For the inherency theory, "usually" isn't sufficient because it concedes that there are times when they don't have angina. This concession, alone, is sufficient to render the Examiner's inherency grounds for the rejection null and void.

If the Examiner proceeds to submit further rejections on the basis of the statement that patients needing cardiopulmonary bypass or cardio-catheterization usually have angina and resulting myocardial ischaemia, Applicant requests that the Examiner provide evidence to support the statement, as none was provided.

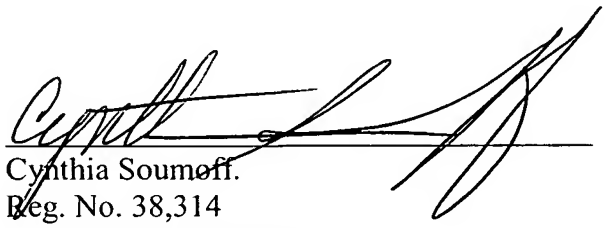
Still further, claims 43, 45 and 46 refer to a method including administering particular polypeptides derived from human lactoferrin that are not disclosed by '247. Claim 43 is directed to a peptide comprising replacements of the normal residues at positions 20, 22 and 26 with A, K and D, respectively. Wu et al only discloses peptides derived from fragments of lactoferrin, not peptides derived from replacing certain residues with other residues. Claim 45 is directed to a peptide *consisting of* 11-17 amino acids in the human lactoferrin sequence that ends at residue 31. Claim 46 is directed to a 12 amino acid peptide *consisting of* the amino acids at residues 20-31 of human lactoferrin. Wu et al never discloses these peptides because Wu only discloses with particularity peptide fragments that extend from the amino-terminus of lactoferrin (Col. 16, lines15-23).

For all the above reasons, Applicant asserts that the claims are novel over the prior art and respectfully requests that the rejections be reconsidered and withdrawn.

In view of the foregoing, Applicant submits that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should the Examiner believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

Dated: November 29, 2007



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